K062682

APR 4 - 2007

510(k) SUMMARY

Submitter: Lake Consumer Products, Inc.
1 Pharmacal Way
Jackson, WI 53037

Contact Person: Mary L. Wundrock
Vice President- Laboratory Services
mwundrock@pharmacalway.com
Phone: (262) 677-4121 Ex 7110
Fax: (262) 677-9006

Date Submitted: September 6, 2006

Proprietary Name: CVS Personal Lubricant & Moisturizer

Common Name: Personal Lubricant

Predicate Name: Astroglide
510(k) Number: K935299

Classification Name:

21 CFR 880.6375 Patient Vaginal Lubricant
Product Code MMS
Class I

21 CFR880.5300 Lubricant, Patient, Vaginal, Latex Compatible
Product Code NUC
Class II

Description of Device:

The CVS Personal Lubricant & Moisturizer formula is non-sterile, clear, non- staining, non-greasy, aqueous gel intended for use as a moisturizer for vaginal dryness and personal lubrication of the vaginal area to enhance condom use and to facilitate ease and comfort during intimate sexual activity. CVS Personal Lubricant & Moisturizer is compatible with latex condoms as demonstrated in condom compatibility testing. This device is not a contraceptive or spermicide, nor does it contain any such component. CVS Personal Lubricant & Moisturizer is packaged in PETE bottles with a foil seal and polypropylene cap.

Intended Use:

CVS Personal Lubricant & Moisturizer is intended as a personal lubricant for vaginal dryness and personal lubrication of the vaginal area to enhance condom use and to facilitate ease and comfort during intimate sexual activity. The lubricous nature of the product helps supplement the body's natural lubricating fluids, thereby reducing friction. CVS Personal Lubricant & Moisturizer is compatible with latex condoms. This device is not a contraceptive or spermicide, nor does it contain any such component.

Comparison of Technological Characteristics:

CVS Personal lubricant & Moisturizer contains water, glycerin, propylene glycol, polyquaterium 15, methylparaben and propylparaben. CVS Personal Lubricant & Moisturizer is substantially similar to the predicate device.

A summary comparison of the features of CVS Personal Lubricant & Moisturizer and the predicate device Astroglide is provided in Table 1.

TABLE 1

Features	CVS Personal Lubricant & Moisturizer	Predicate Device-Astroglide
Labeled Condom Compatible	Yes	Yes
Personal Lubricant	Yes	Yes
Contains Water	Yes	Yes
Contains Glycerin	Yes	Yes
Contains Propylene Glycol	Yes	Yes
Contains Polyquaternium 15	Yes	Yes
Contains Methylparaben	Yes	Yes
Contains Propylparaben	Yes	Yes
Sterile	No	No
Container type	Plastic	Plastic

CVS Personal Lubricant & Moisturizer is substantially equivalent to the following device that is currently in commercial distribution:

Astroglide, BioFilm Inc., K935299

Substantial Equivalence:

CVS Personal Lubricant & Moisturizer is substantially similar to the predicate device, Astroglide. The products have the same intended use and technological characteristics. No new safety or effectiveness issues have been raised through testing. Both products are intended for use as personal lubricants, safe to use with condoms, water-soluble and for over-the-counter (OTC) use.

Summary of Performance Data:

Non-Clinical Studies

Stability- CVS Personal Lubricant & Moisturizer has successfully passed 90 day accelerated stability.

Preservative Effectiveness- CVS Personal Lubricant & Moisturizer formulation with the preservative system has successfully passed the requirements of the USP <1227> Antimicrobial Effectiveness Test.

Comparison with Predicate Device- CVS Personal Lubricant & Moisturizer was compared to Astroglide on the basis of perceptual qualities, physical and chemical properties, ingredient list review, label claims and packaging. Test results rated CVS Personal Lubricant & Moisturizer (a 10 of 10 rating) as comparable to Astroglide.

Condom Compatibility Testing- CVS Personal Lubricant & Moisturizer, when applied to latex condoms does not adversely affect tensile strength, elongation or burst pressure, when compared to untreated condoms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 4 - 2007

Ms. Mary L. Wundrock
Vice President – Laboratory Services
Lake Consumer Products, Inc.
1 Pharmacal Way, P.O. Box 198
JACKSON WI 53037

Re: K062682
Trade/Device Name: CVS Personal Lubricant & Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient lubricant
Regulatory Class: II
Product Code: NUC and MMS
Dated: March 21, 2007
Received: March 22, 2007

Dear Ms. Wundrock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement:

510(k) Number: K062682

Device Name: CVS Personal Lubricant & Moisturizer

Indications for Use:

A non-sterile personal lubricant for OTC consumer use, as a moisturizer for vaginal dryness and personal lubrication of the vaginal area to enhance condom use and to facilitate ease and comfort during intimate sexual activity. CVS Personal Lubricant & Moisturizer is compatible with latex condoms. This device is not a contraceptive or spermicide nor does it contain any such component.

Prescription Use_____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062682